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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,882	08/08/2003	Benjamin Spenser	501015.20512	2524
30452 7590 09/06/2007 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			EXAMINER MATTHEWS, WILLIAM H	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 09/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/637,882	Applicant(s) SPENSER ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-107 is/are pending in the application.
- 4a) Of the above claim(s) 81,82 and 94-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-80,83-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 72-107 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Claims 81,82,94-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1-17-06. The particular limitations which are not readable on the elected species (Fig 1, 9A, and 14A) are the separate leaflets (81,94), fabric layer interposed between the valve assembly and support stent and to which both are stitched (82,95,96). Claims 97-107 depend from claim 96 and are thus not readable on the elected species.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72,73,76-79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,893,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims are broader and therefore fully anticipated by the patented '460 claims, or contain limitations that are obvious variants of the patented '460 claims. Claim 72 provides the limitation "substantially circular profile" which would be inherent, or at least obvious in view of the "annular frame" recited in claim 2 of '460. Claim 76 recites bioprosthetic which is structurally similar to the materials recited in claims 4-6 of '460.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-80,83-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The following limitations are not sufficiently supported by the specification:

Claim 72 (substantially circular)

Claims 74 and 86 (the entire length)

Claims 76 and 89 (bioprosthetic material)

Claims 80 and 93 (valve assembly anchored to both the support beams and web)

Claim 83 (substantially tubular, substantially co-extensively)

Claim 84 (beams terminate at the outlet end of the support stent)

Claims 73,75,77-79,85,87-88,90-92 are rejected for depending from claims including the limitations above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "the collapsible slack portions" lack proper antecedence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 72,73,75,76,80,83-85,87-89, and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Schreck US PN 6,454,799.

Schreck discloses in figures 1-3, lines 16-65 of col. 6, and lines 33-63 of col. 7 a tricuspid heart valve comprising annular (or substantially circular or tubular) stent frame 24, equidistantly spaced rigid support beams 42 with bores 56,80 for stitching the valve thereto which terminates at the outlet end, a collapsible web or mesh structure between the beams, and bioprosthetic leaflets 32.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 77 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Bessler et al. US PN 5,855,601.

Schreck meets the structural limitations of claims 77 and 90 as described above, but lacks the express written disclosure of using nickel-titanium for the stent. Bessler et

al. teach in lines 3-18 of col. 6 a heart valve having a self expanding nickel titanium stent in order to provide a biocompatible means of securement.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using nickel-titanium alloys for the stent, as taught by Bessler et al., in order to provide a biocompatible means of securement for the heart valve.

Claims 78,79,91, and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Rosen US PN 4,345,340.

Schreck meets the structural limitations of claims 78,79,91, and 92, as described above, but lacks the express written disclosure of employing radiopaque markers on the valve. Note lines 1-3 of col. 13 of Schreck describe the use of radiopaque markers, but are unclear as to whether the markers are located on the valve or delivery device. Rosen teaches in lines 19-31 of col. 2 the use of radiopaque markers on a heart valve in order to assist implantation.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by including radiopaque markers, as taught by Rosen, in order to assist the implantation procedure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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